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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/039,191	12/31/2001	Semyon Shchervinsky	ETH-1603	7167	
7590 05/28/2004			EXAMINER		
Selitto, Behr & Kim			SCHAETZLE, KENNEDY		
203 Main Street Metuchen, NJ 08840			ART UNIT	PAPER NUMBER	
2.20 .00.1, 2.0 000.0			3762	3762	
		DATE MAILED: 05/28/2004			

Please find below and/or attached an Office communication concerning this application or proceeding.

		1/1/				
	Application No.	Applicant(s)				
	10/039,191	SHCHERVINSKY, SEMYON				
Office Action Summary	Examiner	Art Unit				
	Kennedy Schaetzle	3762				
The MAILING DATE of this communication appeared for Reply	pears on the cover sheet with the o	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tir ly within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	mely filed ys will be considered timely. I the mailing date of this communication. ED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on						
	— s action is non-final.	:				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under t	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-24</u> is/are pending in the application) .					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6) Claim(s) 1-9,13-17 and 20-24 is/are rejected.						
7)⊠ Claim(s) <u>10-12,18 and 19</u> is/are objected to.						
8) Claim(s) are subject to restriction and/o	or election requirement.					
Application Papers						
9) The specification is objected to by the Examine	er.					
10)⊠ The drawing(s) filed on <u>31 December 2001</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the	• • • • • • • • • • • • • • • • • • • •					
Replacement drawing sheet(s) including the correc	* '	, ,				
11) The oath or declaration is objected to by the Ex	• • • • • • • • • • • • • • • • • • • •	· · · · · · · · · · · · · · · · · · ·				
Priority under 35 U.Ş.C. § 119						
12) Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. & 119/a)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:		, (5) 5. (1).				
· - · - · -						
2. Certified copies of the priority document		ion No				
3. Copies of the certified copies of the prio						
application from the International Burea	•	_				
* See the attached detailed Office action for a list		∍d.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date						
 Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5-31-02</u>. 	6) Other:	ratent Application (PTO-152)				

Application/Control Number: 10/039,191

Art Unit: 3762

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayer et al. (Pat. No. 4,827,940).

Claims 1 and 2 are clearly anticipated.

3. Claims 1, 4, 5, 6, 13, 14, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Bush et al. (Pat. No. 5,683,447).

Regarding the use of a bioabsorbable coating, see col. 7, lines 3-5.

Regarding claim 4, see Fig. 6.

Regarding claims 6 and 14, Fig. 6 shows electrode 22 to be composed of wire with a circular cross-section.

Regarding claims 21 and 22, Fig. 6 shows a bare electrode wire (pacing wire 45) with a distal tip formed into a harpoon-like shape (i.e., a single barb) to establish a conductive anchor. The paragraph abridging columns 6 and 7 discloses the teaching to shield the fixation barb by using a bioabsorbable material.

4. Claims 13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaldach (Pat. No. 5,922,015).

Concerning claim 13, the examiner considers each element 14 (see Fig. 6b) to constitute an anchor with a harpoon-like shape with a single barb.

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Application/Control Number: 10/039,191

Art Unit: 3762

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. (Pat. No. 4,827,940).

Although Mayer et al. do not explicitly refer to a coating of glycosides; a L-lactide; a D-lactide, etc., the courts have long established that the selection of a known material based on its suitability for its intended use is obvious (*Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945)). Clearly the selection any known biocompatible, bioabsorbable material would have been considered obvious by those of ordinary skill in the electrode arts. The applicant gives no criticality in any one specific material over the other, and it would appear that the coatings used by Mayer et al. would work equally as well.

7. Claims 7-9, 15-17, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bush et al. (Pat. No. 5,683,447).

With regards to claim 7, while Bush et al. teach that the pacing hook 28 may have various cross-sectional geometries including circular and rectangular (col. 5, lines 19-27), no discussion as to the nature of the alternate embodiment barb shape is given. Bush et al., however, teach that such a flattened shape allows for flexibility in the lead axis direction, while enabling the hook to be stiff in the transverse direction to reduce the potential for tissue damage upon implant (col. 6, lines 1-6). Those of ordinary skill in the art recognizing the interchangability of the hook, helix and barb mechanisms, would have seen the obviousness of incorporating a distal flattened barb section of the wire 45 in order to take advantage of this property. A similar comment applies to claim 15.

Regarding claims 8 and 16, the examiner considers a flattened barb to be obvious as reasoned above. Such a barb necessarily includes a pair of flat, planar surfaces lying on opposite sides of a plane containing the central longitudinal axis of the wire 45 –one planar surface being represented by that section of the barb that extends directly along the axis of the wire and facing away from lumen 39, and the other planar surface being represented by that section of the flattened barb that is shown in Fig. 6 as lying closest to lumen 39.

Application/Control Number: 10/039,191

Art Unit: 3762

The limitation set forth in claims 9 and 17 is clearly shown in Fig. 6.

Concerning claim 23, note the reasoning used in the rejection of claims 7 and 15 above.

Regarding claim 24, note col. 7, lines 3-5.

Allowable Subject Matter

8. Claims 10-12, 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record does not appear to contain a teaching for incorporating a surgical electrode with a single asymmetrical barb made from a flattened section of multistrand wire. The applicant in the first paragraph of page 11 gives criticality to this feature.

In reference to claim 12, the prior art fails to disclose a temporary cardiac pacing wire comprising an anchor coated with a bioabsorbable material. Prior art temporary cardiac pacing wires are cited that comprise anchors wholly made out of bioabsorbable material, but do not teach to coat the anchor. Any suggestion to coat the prior art anchors would effectively destroy the references.

Conclusion

- 9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Application/Control Number: 10/039,191 Page 5

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS May 26, 2004